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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/583,086	09/06/2007	Concetta C. Fiannaca	118989-06069055	8801
20583	7550	12/03/2010	EXAMINER	
JONES DAY			LE, HOA T	
222 EAST 41ST ST			ART UNIT	
NEW YORK, NY 10017			PAPER NUMBER	
			1788	
			MAIL DATE	
			DELIVERY MODE	
			12/03/2010	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/583,086

Applicant(s)

FIANNACA ET AL.

Examiner

H. (Holly) T. Le

Art Unit

1788

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 September 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 28-58 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 28-58 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/22)
- Paper No(s)/Mail Date _____

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 102 & 103

2. Claims 28-33 and 37-41 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent No 6,589,579 to Ganan-Calvo ("Ganan-Calvo") as applied to the rejection of claims 1-5, 9-13, 18 and 20 set forth in the last office action and further discussed below.

3. Claims 28-32 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent No. 5,628,937 to Oliver ("Oliver") as applied to the rejections to claims and 1 and 3-10 set forth in the last office action and further discussed below.

4. Claims 34-36 and 42-58 are rejected under 35 U.S.C. 103(a) as being unpatentable over 5,628,937 ("Oliver") in view of US 6,589,579 ("Ganan-Calvo") as applied to the rejections to claims 12-17, 19 and 21-27 set forth in the last office action and further discussed below.

Response to Argument

5. Regarding Ganan-Calvo, Applicant argued that the particulate materials of Ganan-Calvo have a narrow particle range and mixed morphologies. This is incorrect. Ganan-Calvo clearly states that the method disclosed yields particles of homogeneous morphology, in particular, hollow sphere morphology. See Ganan-Calvo, page 4, lines

10-11; and also claims 1-7 where method of making hollow spheres of uniform particle size is described.

6. Regarding Oliver, Applicant contended that "there is nothing in Oliver that teaches -much less suggests - that the particulate materials produced exhibit particles that are substantially mono-dispersed and have substantially the same morphology". This is incorrect. Applicant clearly states that the method of making particles of the claimed invention, as well as the apparatus, is "particularly described in WO 94/20204" (instant specification, page 9, lines 1-2). WO94/20204 and the Oliver patent are equivalents, i.e. they contain identical specification. The instant specification and Oliver describe essentially the same method of making particulate materials, and both follow the method of WO94/20204 which comprises: (1) a jet-spray method using acoustic vibration to break up the particles; the flow jet is laminar; applied at the same Weber frequency and Rej number. Compare the method described in the instant specification at page 9, lines 1-26, to the method described in Oliver, in particular, at col. 4, lines 1-4 and 66-67; col. 6, line 65 to col. 7, line 3. More importantly, in Applicant's own disclosure, all particles following the method disclosed in WO94/20204 result in the same morphology, even processed in different ranges of Rej number and/or Weber frequency. The only particles of mixed morphology are particles of samples 20, 25-27, and 32, and the process of making these particles is either by a rotary spray process (samples 20, 25, 26 and 32) or two fluid spray process (Sample 27). Based on this revelation of Applicant's own disclosure, all particles made by Oliver method (which is the method of WO94/20204) necessarily result in the same morphology.

7. Regarding Oliver, Applicant further contended that it's "at best- mere speculation" on the part of the Examiner to suggest an MDI of at most 0.5. This argument is limited to claims 29 and 37 because only these two claims contain the feature that Applicant relies on for this particular argument. Applicant did not offer any concrete evidence to disprove such 'mere speculation' alleging of lack of detailed particle size distribution data in the Oliver patent. Applicant appears to have missed the data provided in the table at column 12, where Oliver reports the particle size distribution and a mean particle size (D_{50}) of 344 microns. Based on this information, the MDI can be calculated as follows:

(Particle size 10%) i.e. D_{10} , ranging from 100-200 and 500-700; which would give a D_{10} of 150 μm in 4%; 600 in about 9%; so the D_{10} would be 500 μm ; and a D_{90} of 300-350 μm ; and then the MDI is:

$$[(D_{90} - D_{10}) / D_{50}] = [(350-500)/344] = \text{less than } 0.5.$$

8. Further on the subject of MDI, all claims -except claims 29 and 37- describe an MDI of at most 1.2. In Applicant's own disclosure, all particles following the method disclosed in WO94/20204 result in an MDI of less than 1.2, even processed in different ranges of Rej number and/or Weber frequency. The only particles that have an MDI of larger than 1.2 are particles of samples 20, 25-27, and 32, and the process of making these particles is either by a rotary spray process (samples 20, 25, 26 and 32) or two-fluid spray process (Sample 27). Based on this revelation of Applicant's own disclosure,

all particles made by Oliver method (which is the method of WO94/20204) necessarily result in an MDI of less than 1.2.

9. Applicant's arguments filed September 20, 2010 have been fully considered but they are not persuasive for the reasons set forth in paragraphs 5-8 above.

Conclusion

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to H. (Holly) T. Le whose telephone number is 571-272-1511. The examiner can normally be reached on 12:30 p.m. to 9:00 p.m. (EST), Mondays to Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Callie Shosho can be reached on 571-272-1123. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/H. (Holly) T. Le/
Primary Examiner, Art Unit 1788

December 1, 2010